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71 Applicant: E.I. DU PONT DE NEMOURS AND COMPANY  
 Legal Department 1007 Market Street  
 Wilmington Delaware 19898(US)

72 Inventor: Benin, Joshua  
 13 Caulfine Court  
 Newark Delaware 19711(US)

72 Inventor: Krauss, Leland Luper  
 63 Hidden Valley Road  
 Aston Pennsylvania 19014(US)

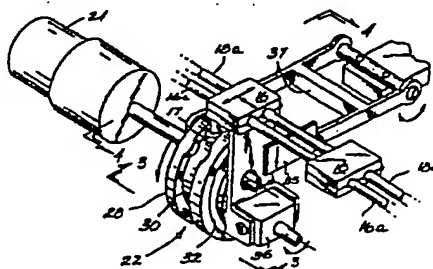
72 Inventor: Roxlo, Helen Elizabeth  
 225 West Park Place  
 Newark Delaware 19711(US)

74 Representative: Jones, Alan John et al,  
 CARPMAELS & RANSFORD 43 Bloomsbury Square  
 London, WC1A 2RA(GB)

54 Automatic splicing device.

57 An apparatus, system, and process for making a sterile connection between two thermoplastic resin tubes (16a,18a) is disclosed. The tubes (16a,18a) are cut by a hot cutting means (35) so as to form a molten interface between the tubes (16a,18a) and the cutting means (35). The tubes (16a,18a) are aligned with each other and slid off an edge of the cutting means (35) while being urged together. As the thermoplastic resin cools a sterile splice is formed. The apparatus is controlled to provide precise timing of the above events and includes safeguards to ensure sterility is maintained.

FIG. 2



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TITLE

## AUTOMATIC SPLICING DEVICE

BACKGROUND OF THE INVENTION

This invention relates to an apparatus,  
5 system and process for forming a sterile connection  
between two plastic tubes.

At the present time there are a number of  
medical and scientific procedures which require the  
sterile transfer of fluids from one container to  
10 another. Two areas in which sterile splicing of  
tubes would be useful are in replacing dialysate  
liquid bags in continuous ambulatory peritoneal  
dialysis (CAPD) procedures, and in processing blood  
in bags to separate components, add treating agents,  
15 etc.

A splicing device which would automatically  
produce sterile splices between two internally  
sterile tubes in a simple, rapid, reliable manner  
would permit one to effect whatever processing is  
20 desired in such areas without compromising sterility.

SUMMARY

The present invention relates to an  
apparatus, system and process for cutting and joining  
two internally sterile tubes using a heated cutting  
25 means while maintaining system sterility. The tubes  
to be joined are cut by the cutting means with molten  
polymer sealing each tube end against the cutting  
means. Seals of molten polymer hot enough to kill  
bacteria quickly are effectively maintained with no  
30 chance for viable airborne or surface bacteria to  
find their way inside either of the tubes or the  
joint. The tube ends are moved into alignment, the  
heated cutting means slid away, and the ends pushed  
together. When the joint cools, the sterile  
35 connection is complete.

The system includes, in addition to the heated cutting means, a pair of mounting blocks adapted to receive and hold the tubes and a family of mechanisms to generate three orthogonal motions required in splicing. These are moving the hot blade and the tubes relative to each other to pass the blade through the tubes, shifting the mounting blocks or clamps holding the tubes relative to each other to align the tube ends to be joined, and finally as the hot blade is moved from contact with the tubes, pushing or urging the mounting blocks together. The system also includes a controller to provide precise timing of the events outlined above for effecting a sterile connection and to provide safeguards to insure sterility is maintained.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is an isometric view of the automatic splicing device of this invention.

Fig. 1A is an isometric view of the blade holder and load and eject device used in the splicing device of this invention.

Fig. 2 is an isometric view partially broken away of the driven cam used to move the clamps and the blade of the splicing device of Fig. 1.

Fig. 3 is a view of Fig. 2 taken along line 3-3.

Fig. 4 is a view of Fig. 2 taken along line 4-4.

Figs. 5A-5D are schematic views of two tubes being positioned, severed, realigned and joined, respectively.

Fig. 6 is an isometric view of the mounting blocks of the splicing device of this invention.

Fig. 7 is a block diagram of the control system for the splicing device of this invention.

Figs. 8A-8D are logic diagrams for the splicing device of this invention.

DETAILED DESCRIPTION OF THE INVENTION

Referring to Fig. 1, the splicing device  
5 chosen for purposes of illustration is denoted generally as 10 and includes as major components a frame 12, a cutter 14 pivotally connected to the frame, a pair of mounting blocks 16, 18 spaced from each other in the same plane, an evacuation pump 20a  
10 driven by a motor 20, a cam cylinder 22 driven by a motor 24 and the electronic control unit 26.

The mechanism for generating the three orthogonal motions required for splicing is seen in Fig. 2 which shows a typical arrangement of that  
15 mechanism. More particularly, it involves three cams to accomplish the three motions. In the preferred embodiment shown, the cams are grooves 28, 30, 32 on different faces of cam cylinder 22. This arrangement ensures that the three cams never get out of phase.  
20 A knife holder 37 for blade 35 is pivotally attached to frame 12 at one end and is engaged in cam groove 28 at its other end. The blade 35 is positioned between mounting blocks 16, 18 and below the tubes 16a and 18a held side-by-side in the blocks for  
25 splicing. A pivoting block 36 is journaled in frame 12 at one end and journaled to mounting block 16 at its other end. Mounting block 16 intermediate to its ends is engaged in cam groove 32. Mounting block 16 is also engaged in peripheral cam groove 30 via  
30 follower 17 while mounting block 18 is fixed to frame 12. Motor 24 rotates cam cylinder 22.

The blade 35 for the cutting knife is an etched stainless steel foil resistor laminated between sheets of copper connected to a battery. In  
35 use, it is subjected to a short heating cycle (about

6 seconds) and to one-shot use (a new blade is used for each splice).

The splicing operation with the apparatus disclosed utilizes three orthogonal motions involving mounting block 16 and the knife blade 35. These are lifting the knife blade 35 through the tubes 16a and 18a, shifting the tubes to align the ones to be joined together and finally urging the tubes together while withdrawing the blade. Figs. 5A-5D.

10 schematically shows this operation and in 5A the mounting blocks 16, 18 and knife blade 35 are shown in the ready position after the blade is heated to operating temperature. The cam cylinder 22 commences rotation (Fig. 4) in the direction of the arrow and

15 with this rotation cam groove 28 lifts knife blade 35 upwardly through the tubes 16a, 18a. With the blade 35 dwelling between the tubes, continued rotation of the cam cylinder causes cam groove 32 to rotate mounting block 16 aligning the tubes 16a, 18a (Fig.

20 5C). Continued rotation of the cam cylinder causes peripheral cam groove 30 to urge mounting block 16 toward fixed mounting block 18 as knife blade 35 is lowered. Thus tubes 16a, 18a are pushed together forming a sterile splice between them (5D).

25 As best shown in Fig. 6, the tube mounting blocks 16, 18 include covers 40, 42 pivotally attached at hinge points 43, 44 to tube holder bases 46, 48. The fixed mounting block 18 has a relief groove 47 cut in its cover 42 with a matching groove

30 47a in its holder 48 to accommodate an old splice. Channels 16b, 16c are provided in mounting block 16 to hold the tubes to be spliced and mounting block 18 is similarly equipped with channels 18b, 18c. Mounting block 16 is also shown with a closed end to

35 channel 16c to position the tube and permit finger

access for removal of the severed off end of tube 18a. The channel 16b in cover 40 is provided with a web 16d and the channels 18b and 18c in cover 42 are provided with webs 18d and 18e for the purpose of  
5 clamping the tubes positively in place when the covers are latched in place over the lips 46a and 48a of the respective bases 46, 48. Also incorporated in the mounting block 18 is a passage 50 in the base 48 that is connected to evacuation pump 20a. Passage 50  
10 is in communication with recess 52 in cover 42 and intersecting channel 54 when mounting block 18 is closed to pull air above the tubes as they are being melted by the hot knife 35. The fumes from the splicing operation are drawn off and filtered in a  
15 filter (not shown) attached to the inlet of pump 20a. The mounting block 16 also has a channel 56 in its cover 40 to provide a direct path for air to be drawn above the tubes into the cover 42.

The knife blade load and eject system is  
20 best seen in Fig. 1A and includes a blade magazine 70, a blade load-eject pusher lever 72, blade holder 37, blade clamp 37b and a track 37a in the blade holder. A pair of spring loaded electrical contacts 39, 39a joined by leads 41 to controller 26 are  
25 making contact with the blade 35.

Fig. 7 is a block diagram of the control system of the splicing device described above and includes a controller 26 coupled to a keyboard 66 which includes push buttons 66a, 66b, 66c labelled  
30 Battery, Ready and Start, respectively. A battery 64 and its associated charger 64a as well as certain limit switches designated generally as 68 and an analog to digital converter 62 provide inputs to the controller which in turn controls the operation of  
35 the heating of knife blade 35 and the operation of

cam motor 24 and evacuation pump motor 20. The controller 26 comprises an 8-bit microprocessor No. ID 8085AH, a programmable read only memory No. ID 8755A and a programmable random access memory  
5 No. ID 8155H, all by Intel. The A/D converter 62 is a No. ADC 0802LD by National Semiconductor.

With reference to the logic flow diagrams 8A-8D the operation of the automatic splicing device of this invention will be described as it would be  
10 used by a CAPD patient.

First of all, it should be noted that to insure patient safety from shock in CAPD applications, the unit is powered by a 24 volt DC rechargeable battery 64 and control circuitry is  
15 included that turns off the device in the cycle if the charger 64a is plugged in.

Initially the patient does not have any tubes in the mounting blocks 16, 18 and the unit must be reset from the last splice cycle and the battery  
20 condition checked. The patient pushes the "BATTERY" button 66a which causes the control system to check that the battery has an acceptable charge and turn on the motor 24 to rotate a cam cylinder 22 which resets the moveable clamp 16 to the start position and  
25 actuates the "home" position switch (not shown). The patient then places the tubes to be spliced in the mounting blocks 16, 18 and latches the covers 40, 42 which actuates switches (not shown) that indicate the mounting blocks are closed.

30 The patient pushes the "READY" button 66b which causes the control system to turn on the electronics, check that a blade magazine is installed, and check that the mounting block covers are closed.

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The patient pushes the blade load/eject lever 72 forward which cams open the electrical 39, 39a contacts to the blade 35 and opens the blade clamp 37b, pushes against a blade 35 from the blade magazine 70 which then pushes against other blades in the blade holder to cause the previously used blade 35 to be ejected and a fresh blade to be positioned for the next splice, (NOTE: If the blade magazine is empty, the blade pusher in the magazine mechanically blocks the blade loader/ejector from completing its forward stroke) and actuates a forward switch (not shown) that indicates a fresh blade is properly positioned for the next splice.

The patient retracts the blade load/eject lever 72 which releases the blade clamp 37b to clamp the blade, releases the electrical contacts 39, 39a to press against the blade contact surfaces, releases the next blade in the blade magazine to position it for the next load/eject cycle and actuates a retract switch (not shown) that indicates the lever is retracted and the electrical contacts and blade clamp should be engaged.

The patient pushes the "START" button 66c which causes the control system to turn on the fume evacuation pump 20, check that the blade load/eject lever 72 went forward and back and a magazine 70 was in position, recheck that the tube clamp covers are latched, turn on constant current to the blade and check the voltage after 0.5 seconds to determine if the blade contact and integrity are good. If the above are OK, the control system continues applying constant current to the blade to preheat it for the splice and monitors voltage and time during the preheat cycle to verify the blade integrity and determine when the temperature is right for making a



sterile splice. When the proper temperature is reached for the splice, the control system checks that the clamp covers are still closed and the blade load/eject lever is retracted and actuates the splice relay (not shown) that provides a latched electrical circuit for the blade current and motor 24 so the splice can be completed independent of the microprocessor. This latched circuit insures high reliability for the actual splice operation when the sterility of the tubing is being threatened.

The splice motor 24 rotates the cam cylinder 22 which completes a splice and actuates a switch (not shown) that unlatches the splice relay which turns off the motor 24 and blade current.

The control system then turns off the fume evacuation pump motor 20 and checks the minimum voltage monitored during the splicing operation to ensure the temperature remained high enough to guarantee the sterility of the splice and activates an alarm if it isn't.

25

30

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CLAIMS:

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1. An apparatus for forming a connection between two thermoplastic tubes comprising: a pair of displaced mounting blocks for holding said tubes in a side-by-side relationship; a heated cutting means located between the blocks, said blocks being movable with respect to each other and with respect to the cutting means; means for providing movement between said mounting blocks and said cutting means, said means for providing movement generating three orthogonal motions; and a controller coupled to the means for providing movement to control the timing of the operation of the apparatus.

2. The apparatus as defined in claim 1, said means for providing movement being a driven cam cylinder containing one groove in each face and one groove around its periphery, one of said mounting blocks being coupled to the groove in one face of said cam and to the groove around the periphery of the cam, said cutting means being coupled to the other face of said cam.

3. The system as defined in claim 1 or 2, including an evacuation pump, said mounting blocks having a passage in communication with a separation between said mounting blocks above said tubes at its one end and said passage being in communication with said pump at its other end.

4. The system as defined in claim 1, 2, or 3, movement of said mounting blocks being pivoting movements.

5. A system for automatically forming a connection between two thermoplastic tubes comprising: a frame; cutting means movably mounted to said frame; means for heating said cutting means; a pair of mounting blocks adapted to receive and hold

said tubes in a side-by-side relationship, said blocks being movable relative to each other to first, second, and third positions, the cutting means being between the mounting blocks in the first position, 5 said mounting blocks being relatively displaced in said second position to align two different tube ends facing each other, said mounting blocks being separated from said cutting means in said third position while said mounting blocks are urged 10 together; means for providing movement between the heated cutting means and both of said mounting blocks, said movement passing the cutting means through said tubes when the mounting blocks are in said first position and withdrawing said cutting 15 means from the contact with said tubes when said mounting blocks are in said third position; and a controller coupled to the means for heating the cutting means, and the means for providing movement between the mounting blocks and the cutting means to 20 precisely control the timing of the operation of said system to automatically obtain a connection between the tubes.

6. The system as defined in claim 5, said means for providing movement between said mounting 25 blocks and said cutting means generating three orthogonal motions.

7. The system as defined in claims 5 or 6, said means for providing movement between the mounting blocks and said cutting means being a driven 30 cylindrical cam containing one groove in each face and one groove around its periphery, one of said mounting blocks being coupled to the groove in one face of said cam and to the groove around the periphery of the cam, said cutting means being 35 coupled to the other face of said cam.

8. The system as defined in claim 5, 6, or 7, including an evacuation pump, said mounting blocks having a passage in communication with the separation between said mounting blocks above said tubes at its one end and said passage being in communication with said pump at its other end.

9. The system as defined in/claims 5/<sup>any one of</sup> to 8, the movement of said mounting blocks being pivoting movements.

10. A system for automatically forming a connection between two thermoplastic tubes comprising: a frame; cutting means movably mounted to said frame; means for heating said cutting means; a pair of mounting blocks adapted to receive and hold said tubes in a side-by-side relationship, said blocks being movable relative to each other; means for moving said mounting blocks to first, second, and third positions, the cutting means being between the mounting blocks in the first position, said mounting blocks being relatively displaced in said second position to align two different tube ends facing each other, said mounting blocks being separated from said cutting means in said third position while said mounting blocks are urged together; means for moving the heated cutting means through both of said tubes when the mounting blocks are in said first position and withdrawing said cutting means from the contact with said tubes when said mounting blocks are in said third position; and a controller coupled to the means for heating the cutting means, the means for moving the mounting blocks and the means for moving the cutting means to precisely control the timing of the operation of said system to automatically obtain a connection between the tubes.

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11. The system as defined in claim 10, said means for moving said other mounting block and said means for moving the cutting means generating three orthogonal motions.

5 12. The system as defined in claims 10 or 11, said means for moving said mounting blocks and said means for moving said cutting means being a driven cylindrical cam containing one groove in each face and one groove around its periphery, one of said  
10 mounting blocks being coupled to the groove in one face of said cam and to the groove around the periphery of the cam, said cutting means being coupled to the other face of said cam.

13. The system as defined in claim 10, 11, or 12,  
15 including an evacuation pump, said mounting blocks having a passage in communication with the separation between said mounting blocks above said tubes at its one end and said passage being in communication with said pump at its other end.

20 14. The system as defined in/claims 10/, the movement of said mounting blocks being a pivoting movement. any one of to 13,

15. A system for automatically forming a sterile connection between two thermoplastic  
25 internally sterile tubes comprising: a frame; cutting means pivotally mounted to said frame; means for heating said cutting means; a pair of mounting blocks adapted to receive and hold said tubes one of said blocks being fixed to said frame, the other  
30 being movable; means for moving said other mounting block to first, second, and third positions, the cutting means being between the mounting blocks in the first position, said mounting blocks being relatively displaced in said second position to align  
35 two different tube ends facing each other, said

mounting blocks being separated from said cutting means in said third position while said mounting blocks are urged together; means for moving heated cutting means through both of said tubes when the  
5 mounting blocks are in said first position and withdrawing said cutting means from the contact with said tubes when said mounting blocks are in said third position; and a controller coupled to the means for heating the cutting means, the means for moving  
10 the mounting blocks and the means for moving the cutting means to precisely control the timing of the operation of said system to automatically obtain a sterile connection between the internally sterile tubes.

15 16. A process for forming a connection between two thermoplastic tubes being held in a side-by-side relationship in a pair of displaced mounting blocks movable relative to each other and movable with respect to a heated cutting means  
20 between the blocks comprising: passing the cutting means through the tubes; shifting the blocks to align two different cut tube ends facing each other while maintaining contact between the cut tube ends and the cutting means; and withdrawing the cutting means from  
25 contact with the tubes while urging the blocks together, said passing, shifting and urging steps being orthogonal motions; and controlling the timing of said process to automatically obtain said connection.

30

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FIG. 1

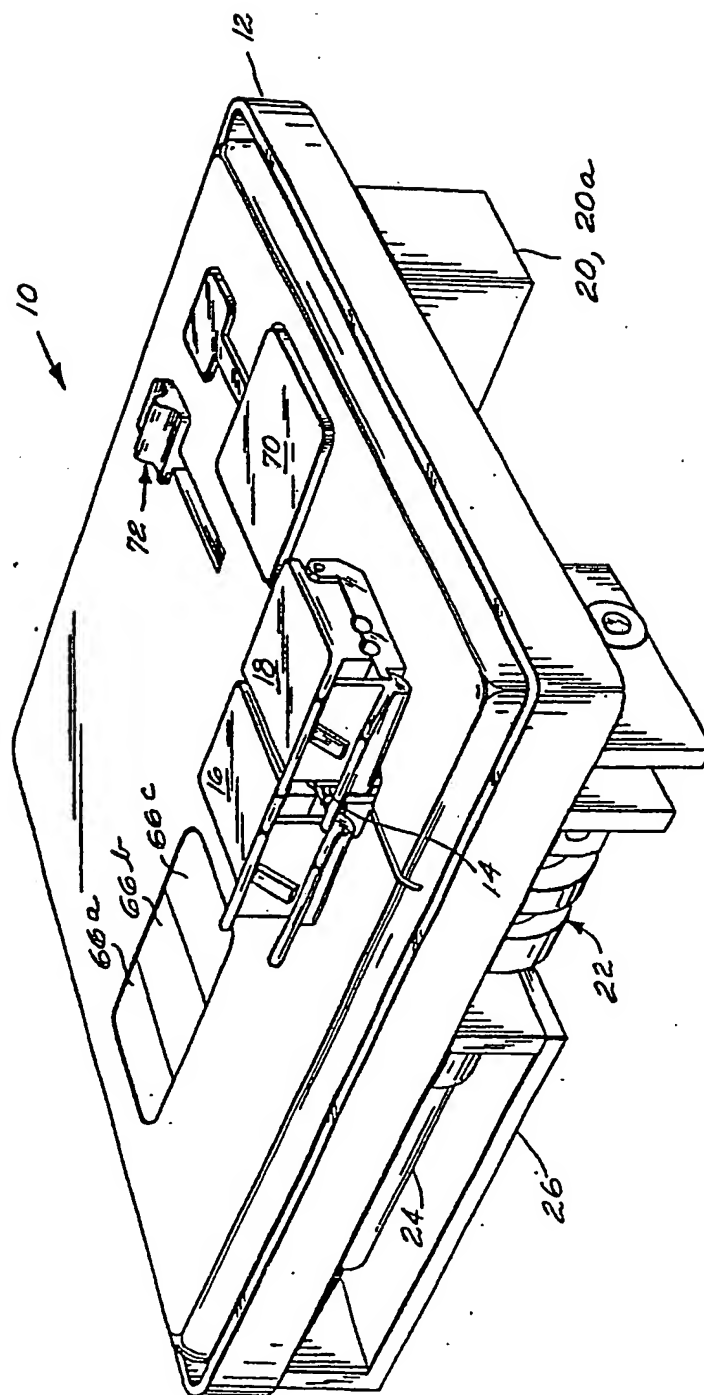


FIG. 1A

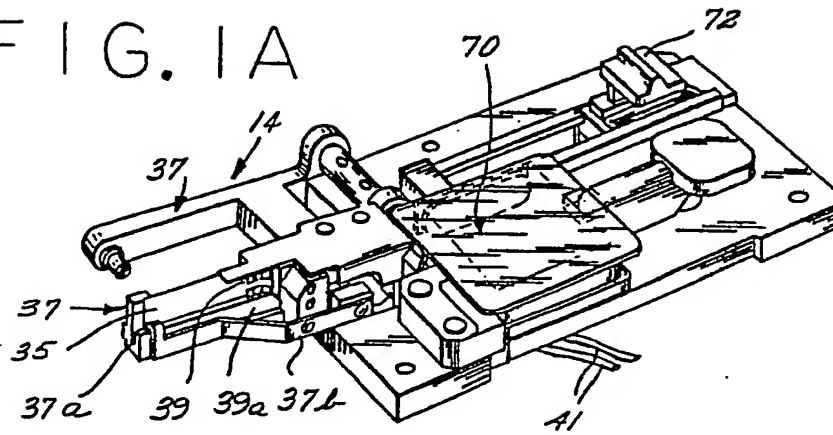


FIG. 2

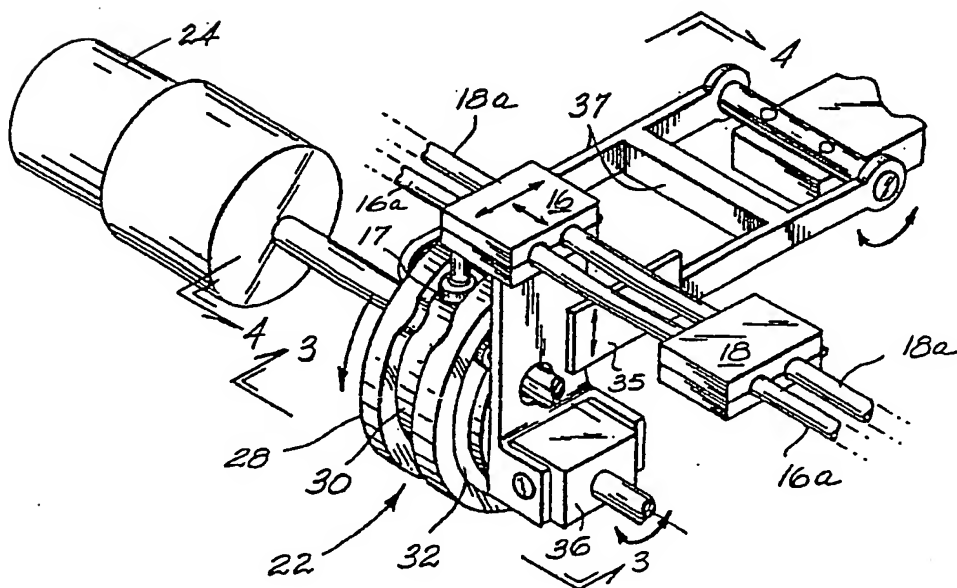




FIG. 3

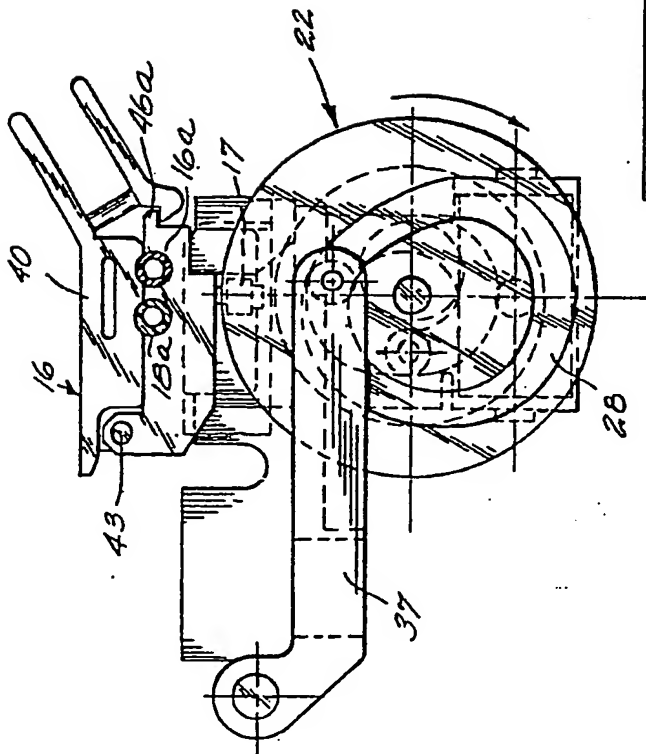
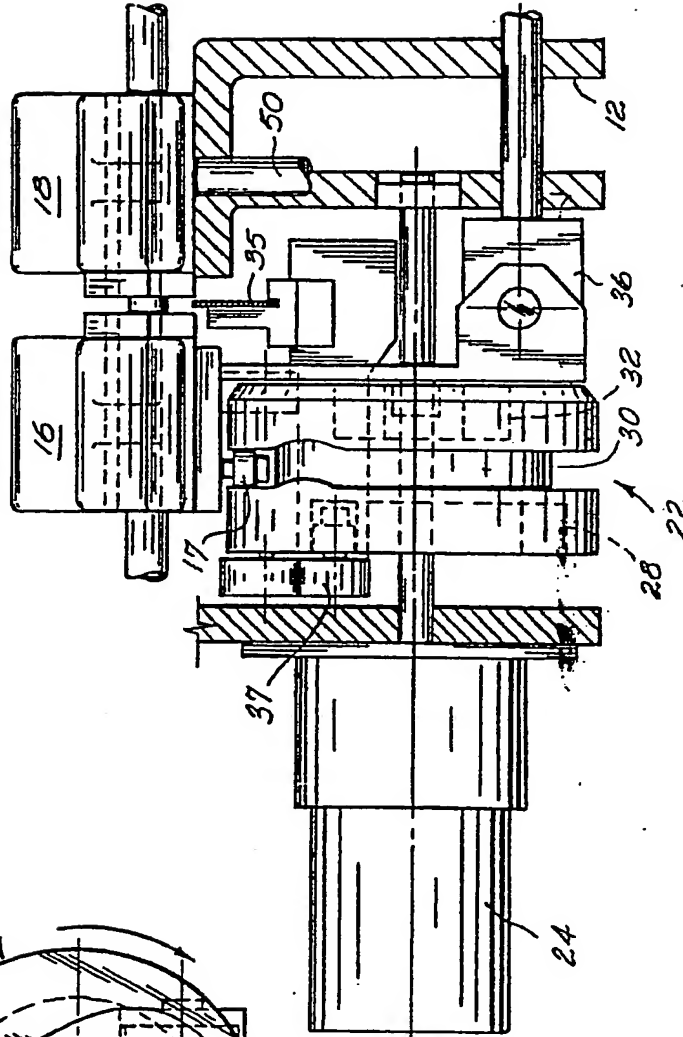
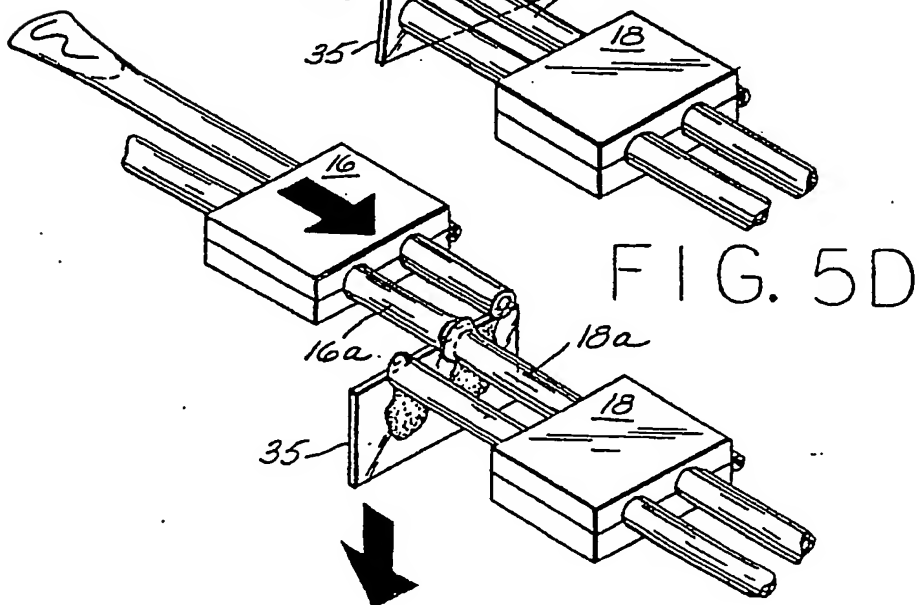
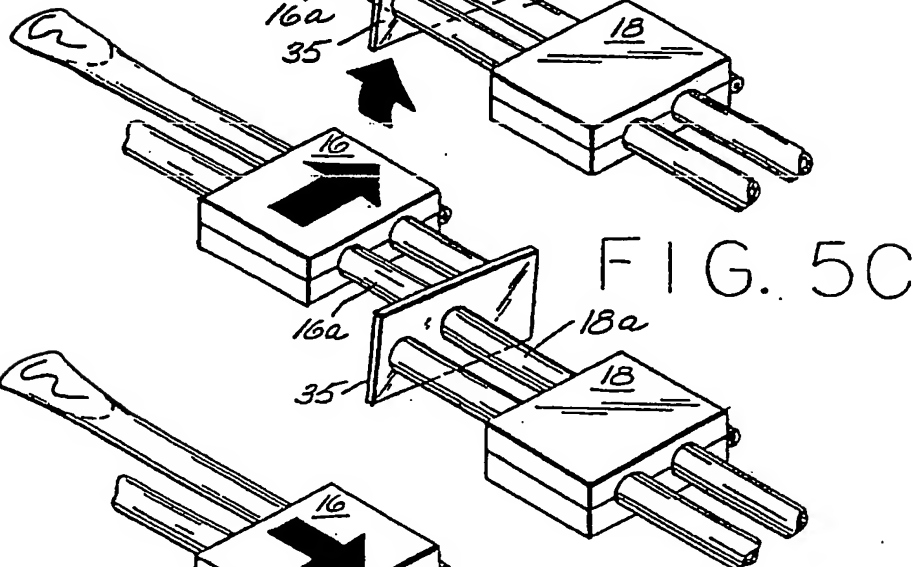
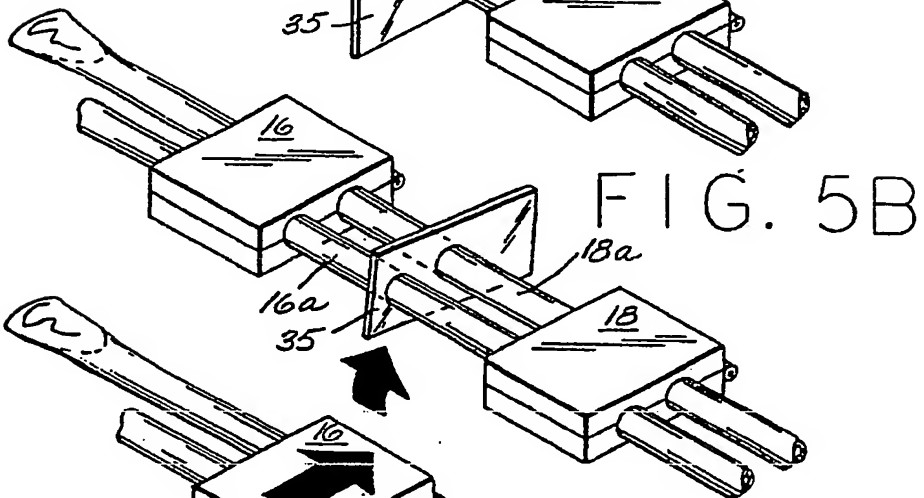
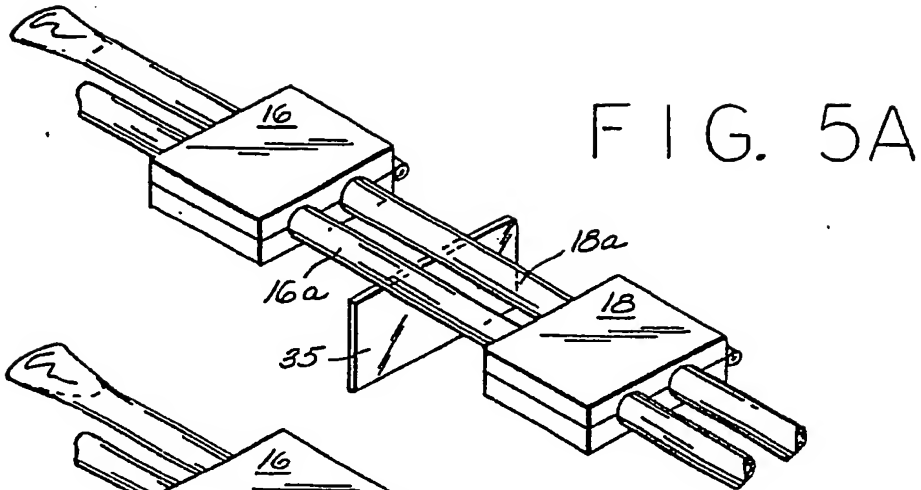


FIG. 4



F I G. 6

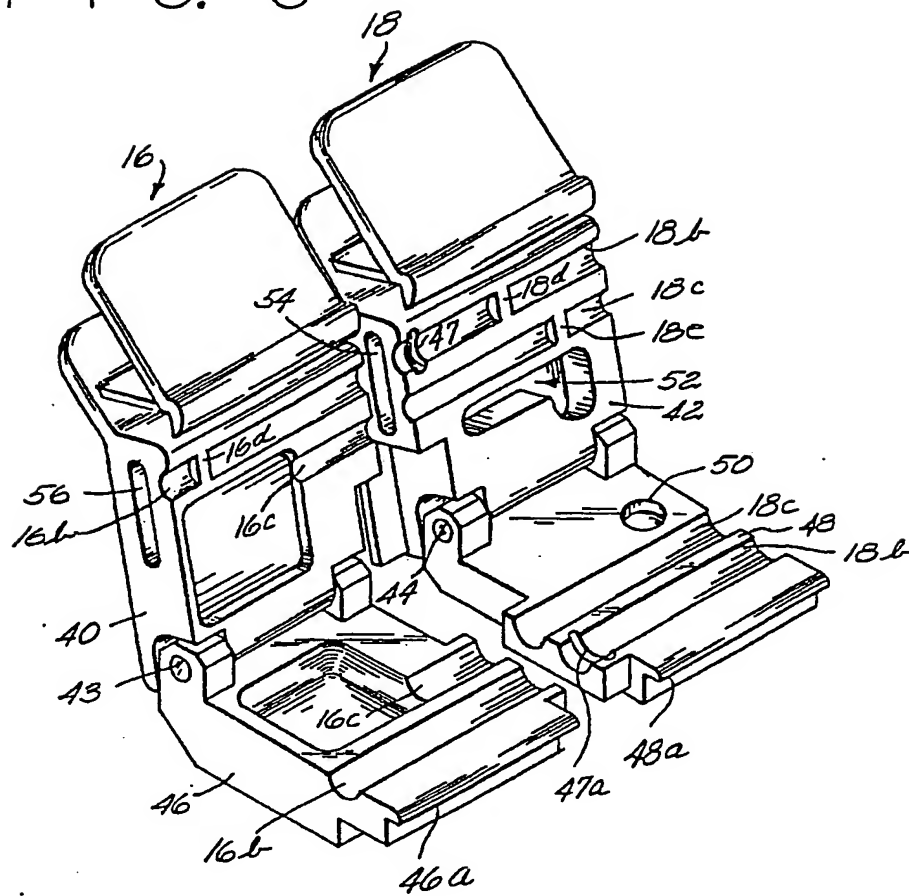
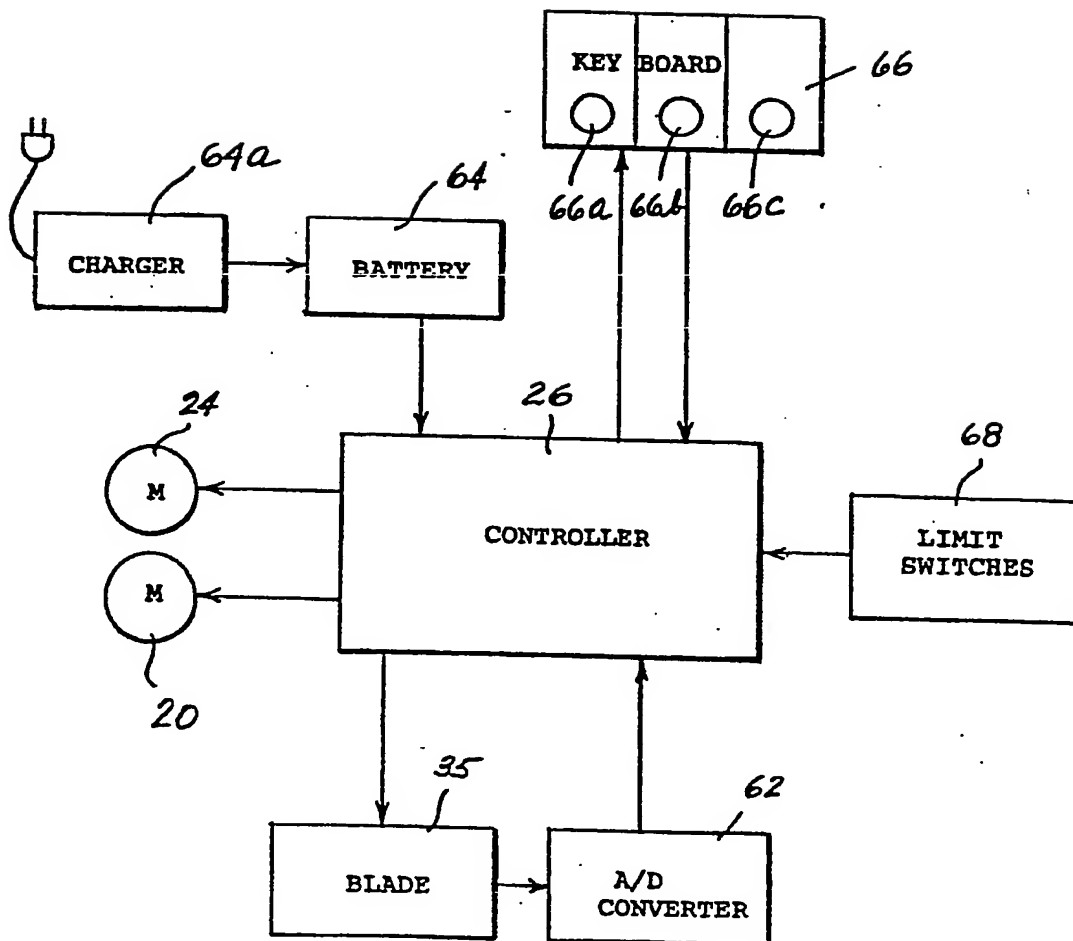
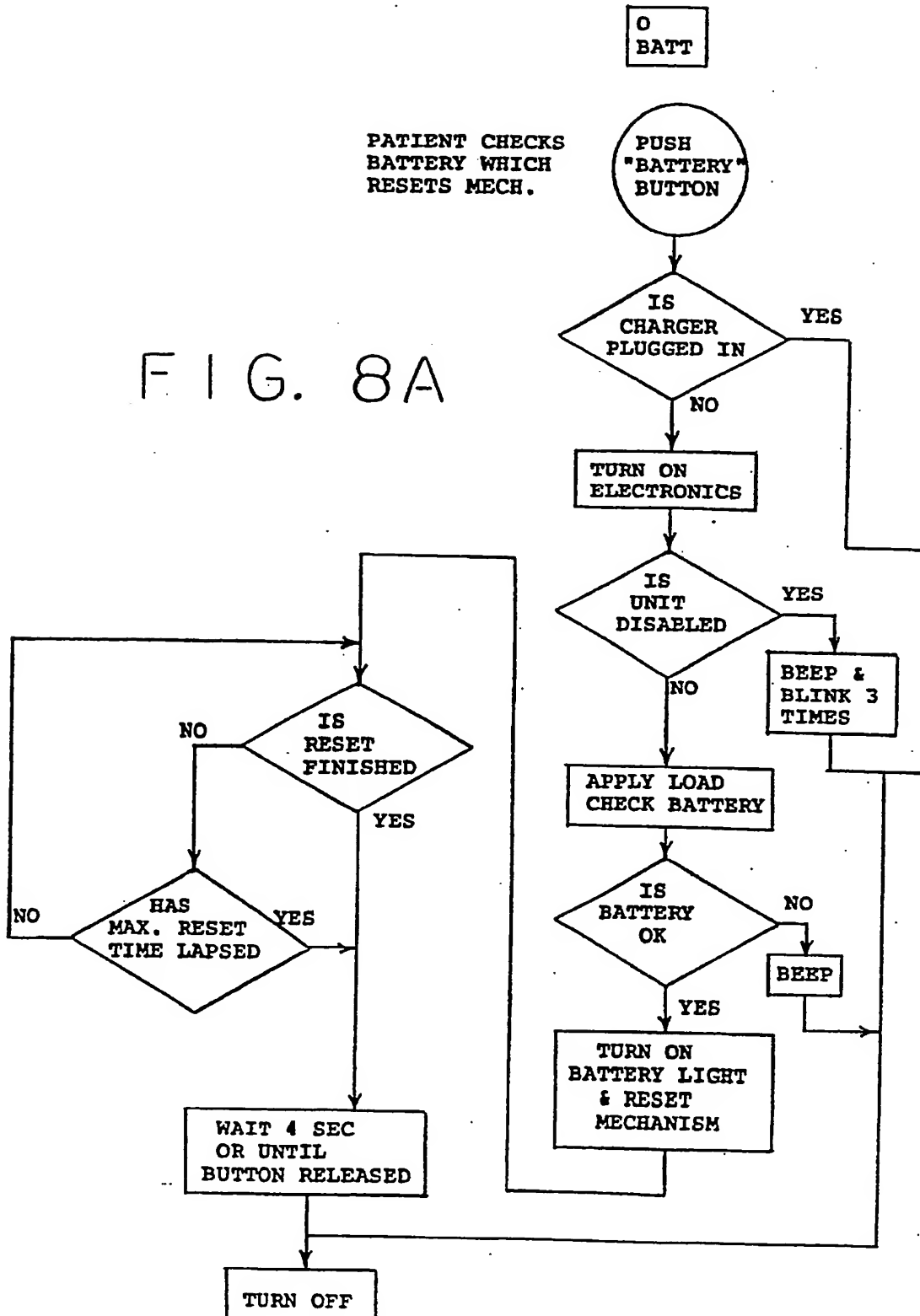


FIG. 7



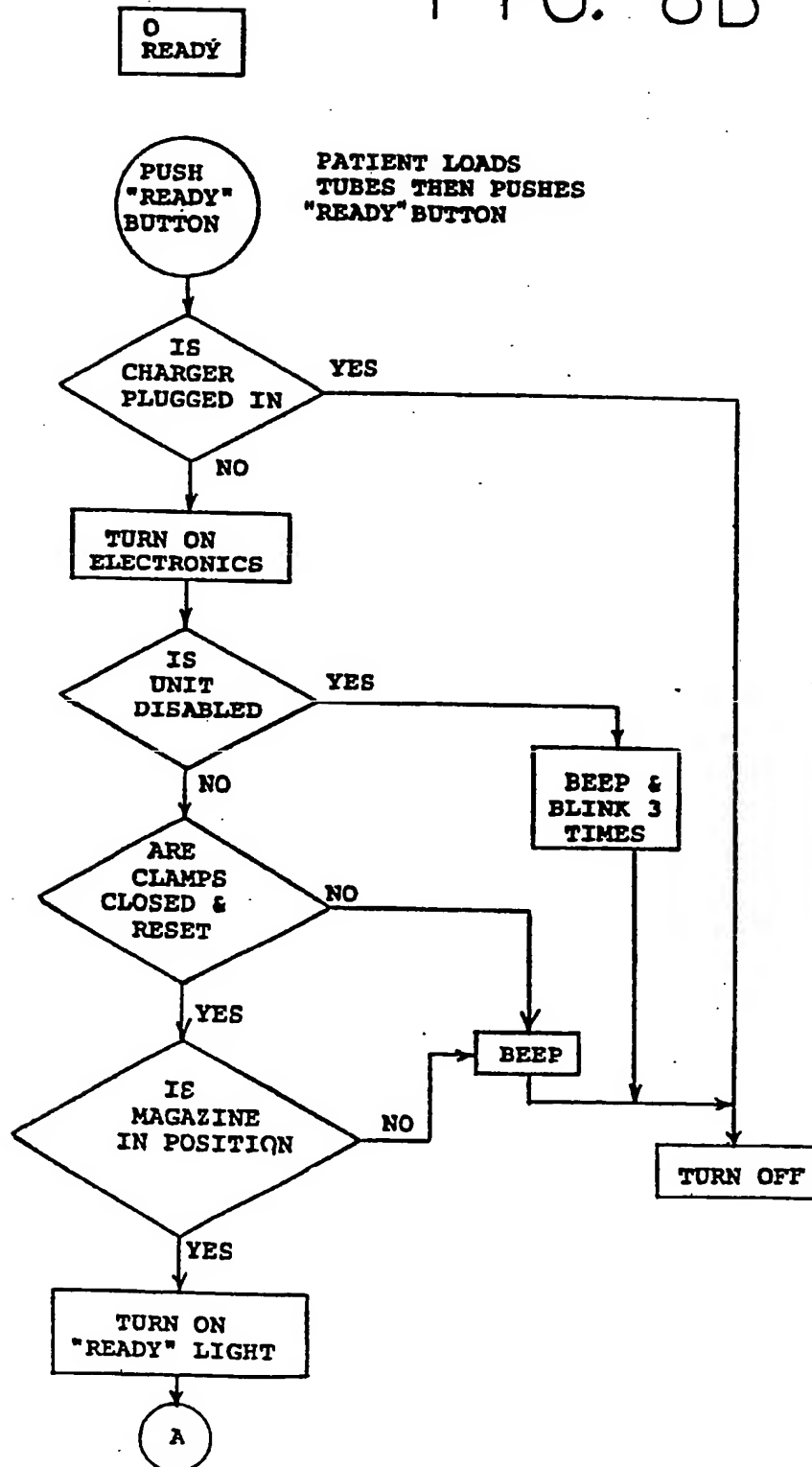
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FIG. 8A



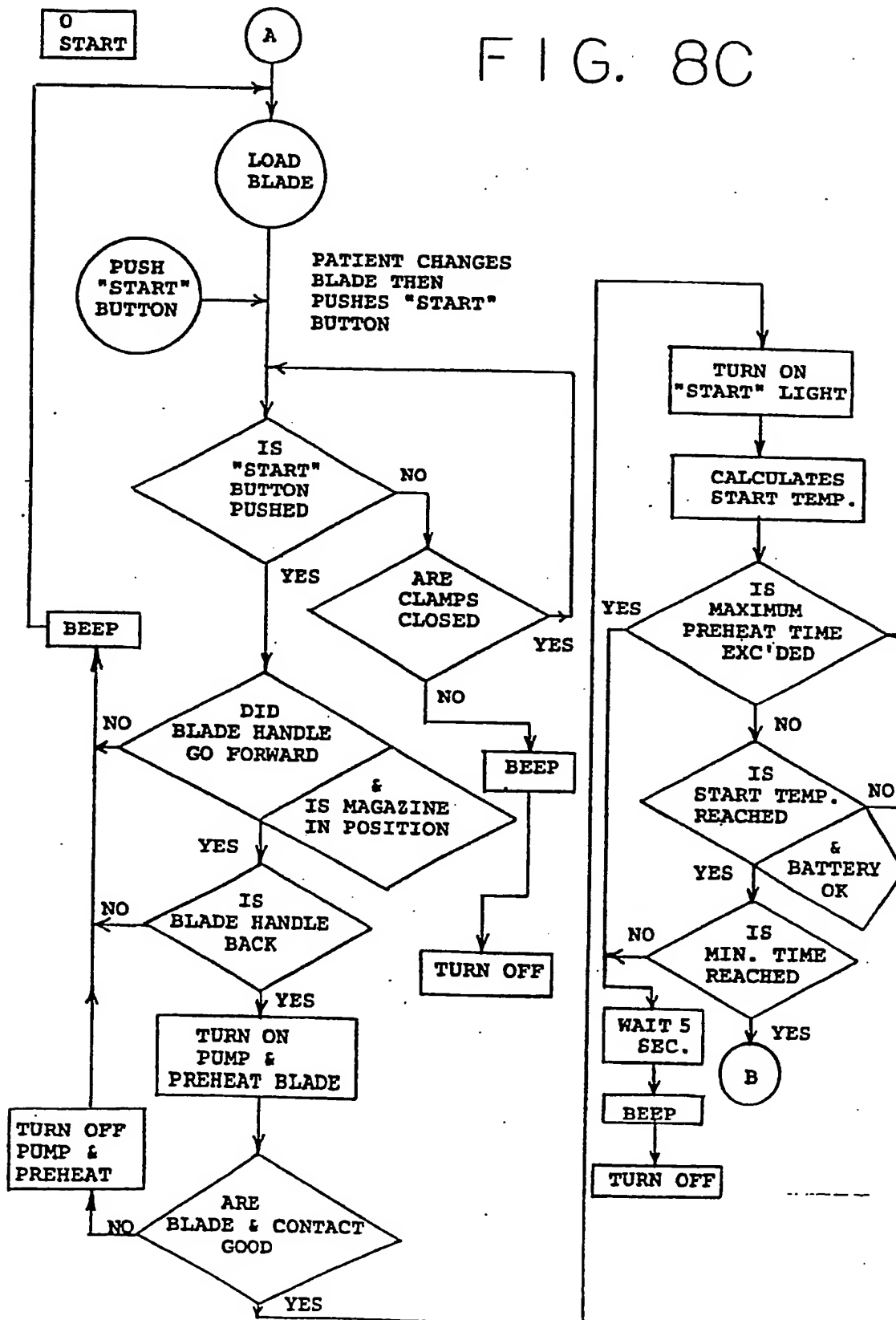
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FIG. 8B



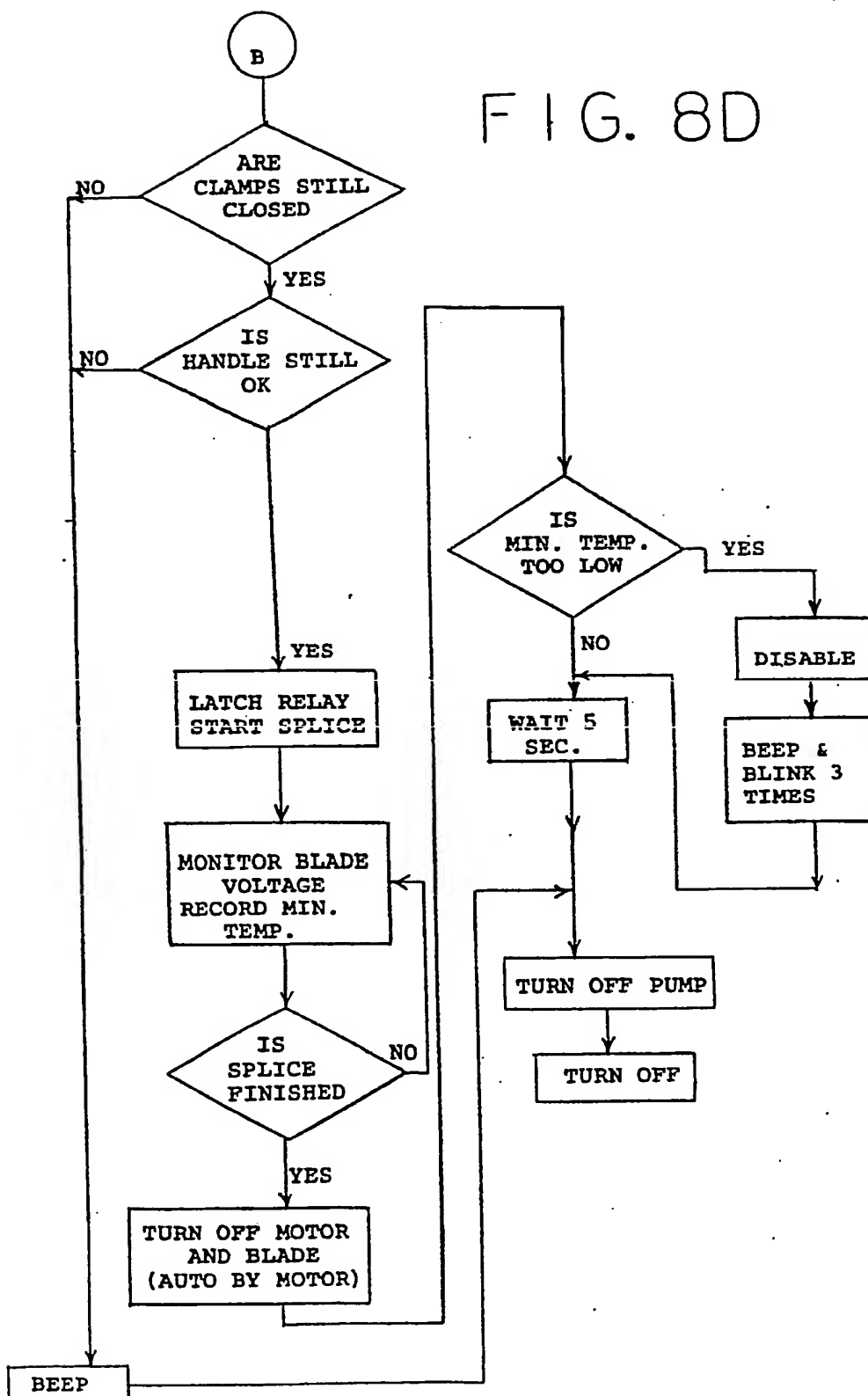
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FIG. 8C



10/10

FIG. 8D







European Patent  
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# EUROPEAN SEARCH REPORT

0105587

Application number

DOCUMENTS CONSIDERED TO BE RELEVANT			EP 83304692.3
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl. 7)
A	<u>EP - A2 - 0 044 204</u> (E.I. DU PONT) * Totality * --	1,4,5, 9,10, 14-16	A 61 M 1/03 B 29 C 27/06 F 16 L 47/02
A	<u>US - A - 3 897 296</u> (J.E. WALDRUM) * Fig. 1-5,8; column 3, line 66 - column 4, line 64; column 5, line 50 - column 6, line 36; column 6, line 50 - column 9, line 68 * --	1,3,5, 8,10, 13,15, 16	
A	<u>US - A - 4 022 256</u> (R.M. BERKMAN et al.) * Totality * ----		
The present search report has been drawn up for all claims			
			TECHNICAL FIELDS SEARCHED (Int. Cl. 7)
			A 61 M 1/00 A 61 M 5/00 A 61 M 25/00 B 29 C 27/00 F 16 L 47/00
Place of search		Date of completion of the search	Examiner
VIENNA		14-12-1983	LUDWIG
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